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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,281	02/27/2004	Jochen Goerlitzer	DEAV2003/0015 US NP	8059

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ROSS J. OEHLER
SANOFI-AVENTIS U.S. LLC
1041 ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

EXAMINER	
COPPINS, JANET L	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,281	GOERLITZER ET AL.	
	Examiner	Art Unit	
	Janet L. Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *1 and 19-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

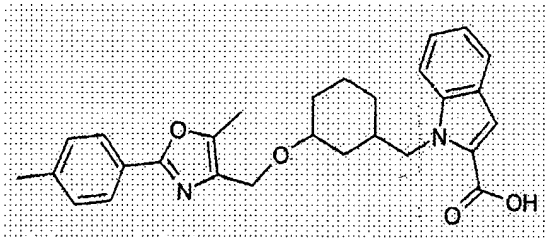
1. Claims 1-30 are pending in the instant application.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement (IDS), submitted October 13, 2005, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, attached to the instant Office Action.

Election/Restrictions

3. Applicant's election of Group I, claims 1-23, directed to compounds of formula I and their compositions, in the reply filed on November 29, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants also elect the specific compound of Example XXVI, found on pages 77-78 of the Specification:



Accordingly, claims 24-30 are currently withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

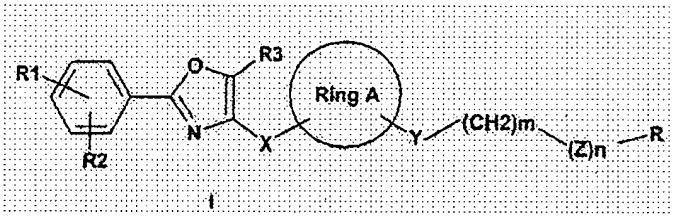
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Status of the Claims

5. Claims 1-30 are pending in the instant application. Claims 24-30, as previously stated, are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:



I

Compounds of formula I, depicted in claim 1, wherein: **Ring A** is cyclohexane; and the remaining variables are as defined.

As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 1-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Accordingly, compounds of formula I of claims 1 and 19-23 wherein Ring A is **not** cyclohexane are currently excluded from consideration. The withdrawn compounds contain varying functional groups such as cyclopentane, phenyl, furan, pyran, dioxin, etc which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. and international classification systems. Therefore the subject matter which are

withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly and a reference that anticipates the elected compound(s) would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as not being fully enabled. While various active ingredients may be listed in the specification, the claims are not enabled for *all* additional agents as claimed since there is no indication as to the full range of active ingredients that could be utilized.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is a pharmaceutical composition, containing a compound of claim 1 and one or more additional "active ingredients."

The state of the prior art and the predictability or lack thereof in the art

It is well recognized in the medical art that treatment of diseases or symptoms are not analogous terms. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Also, in the absence of a showing of correlation between *all* of the agents encompassed by claims 20 and 21 and the compound of claim 1, one of skill in the art is unable to fully predict possible results from the administration of the claimed compounds.

The amount of direction or guidance present and

the presence or absence of working examples

Treatment of specific diseases or disorders is normally disease or symptom oriented, thus are highly individualized, i.e. a composition for treating dyslipidemia (requires an additional statin agent) would not employ the same agents as a composition for treating insulin resistance (requires an additional antidiabetic). If Applicants allege that treating said disorders benefit from the modulation of PPAR, then Applicants must demonstrate that a composition for modulating the biochemical pathway of PPAR and all of the possible combinations of compositions of claims 20 and 21 are inexorably linked. Applicants have provided no support in the Specification for the additional "active ingredients" recited, other than the laundry list found on pages 17-24. The efficacy of a pharmaceutical composition intended for treatment of a specific disease/disorder needs to be specifically and individually supported by factual evidence. The

data provided in the disclosure is insufficient evidence for all possible compositions claimed. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F2d 685, 140USPQ 471; *In re Barr* et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The breadth of the claims

Applicants are claiming a composition containing a broad number of additional ingredients, agents or inhibitors. The argument that the agents claimed by the Applicants are dependent upon the disease being treated is insufficient support that the Applicants are enabled for all vasodilator agents, modulatory agents, etc.

The quantity of experimentation needed

Applicants discuss additional agents on pages 17-24 of the Specification. However, the instant disclosure has not enabled the skilled practitioner to practice the claimed invention with each and every additional active ingredient encompassed by the language of claims 20 and 21. The disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compositions which fall within the scope of a claim will possess the desired effect when administered to a patient in need thereof.

The argument that the various agents claimed by the Applicants are antidiabetics or are all lipid modulators is insufficient support that the Applicants are enabled for ***all*** agents of claim 20 or all agents that have favorable effects on metabolic disturbances. The quantity of experimentation needed is undue. One of ordinary skill in the art without direction, would be unable to test each and every combination encompassed by claims 20 and 21.

One of skill in the art would need to determine whether the claimed composition would provide treatment of all of the disorders/conditions intended, and there are certainly hundreds of combinations of compositions encompassed by the claim. Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine whether the claimed composition would in fact treat the targeted disorder.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds and agents exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad recitation of any or all agents, ingredients, inhibitors, etc of claims 20 and 21. As a result, necessitating one of skill to perform an exhaustive search for which claimed compositions can be utilized.

The Examiner suggests claiming some specific agents that are enabled by the Specification or in literature, and to provide support for the recited compositions.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-19 provisionally rejected on the ground of nonstatutory double patenting over claims 1-9, 11, and 12 of copending Application No. 10/789,865 and claims 1- 20 of Application No. 11/097,345. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on that copending applications since the referenced copending applications and the instant application are claiming common subject matter, as follows: all three applications are directed to 2-phenyl-oxazolyl compounds of formula I that are modulators of PPAR, wherein "Ring A" can be cycloalkyl; and "R" of the instant application is either phenyl (all three applications) or heteroaryl (the same as "Ring B" in the '865 Application).

10. Claims 1-23 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,884,812 and claims 1-7 of U.S. Pat. No. 6,624,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because both patents claim compounds of formula I that possess PPAR-modulatory activity, that read on the compounds of the instant invention, wherein "**R**" is optionally substituted phenyl, "**X**" is C_{1-2} alkyl containing one oxygen atom; one of either "**Y**" or "**Z**" is oxygen and the other is not present; and "**m**" is 1. It would have been obvious for one skilled in the art to make compounds of the same formula I as disclosed in the above patents, and pick and choose from the substituents recited in the claims since compounds of the instant application have the same activity of modulating PPAR.

Claim Objections

11. Claims 1 and 19-23 are objected to for containing non-elected subject matter.

Conclusion

12. In conclusion, claims 1-30 are pending, claims 24-30 are currently withdrawn, claims 1-23 are rejected, and claims 1 and 19-23 are also objected to.

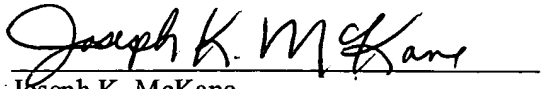
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
January 5, 2007



Joseph K. McKane
SPE, Art Unit 1626